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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Cynthia B. Wilder, Ph.D.

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53, 59-67 and 77-104 is/are pending in the application.
- 4a) Of the above claim(s) 67, 77 and 87-104 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-53, 59, 65, 66 and 78-86 is/are allowed.
- 6) ☒ Claim(s) 3, 10, 34, 39, 40, 60, 61 and 64 is/are rejected.
- 7) ☒ Claim(s) 62 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, Claims 1-53, 59-66 and 78-86 and SEQ ID NOS: 6, 7, 16 and 17 on January 26, 2004 is acknowledged. Claims 54-58, 68-76 have been canceled. Claims 1-53, 59-67, and 77-104 are pending. Claims 67, 77, and 87-104 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-53, 59-66 and 78-86 are discussed below.

Information Disclosure Statement

2. The Information Disclosure Statement (PTO-1449) filed on January 22, 2003 is acknowledged. However, copies of the non-patent references cited therein are not in the instant application. The examiner is making efforts to locate these references; however, resubmission of these documents, if possible by Applicant would facilitate their consideration and would be greatly appreciated by the examiner. A signed copy of the 1449 will be mailed as soon as the examiner obtains copies of the references. The examiner regrets any inadvertent inconveniences.

Claim Rejections - 35 USC § 112

3. Claims 3, 10, 34, 39, 40, 81, 84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 3, 10, 34, 39, 40, 81 and 84 are indefinite for the recitation of " β -GUS" and "CEA" because abbreviations often have more than one meaning in the art. It is suggested inserting the full name of the abbreviations into the claims as supported by the specification as originally filed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 60 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim (PCR Applications Manual, Boehringer Mannheim GmbH, Germany, 1995. Regarding claim 60, Boehringer Mannheim teaches conducting a reverse transcription reaction on an RNA sample in a reaction mixture to produce a DNA sample, adding a PCR reagent composition containing a PCR primer set and a thermostable DNA polymerase to the reaction mixture and conducting a PCR amplification on the reaction mixture (see page 83). Therefore, Boehringer Mannheim et al. meet the limitations of claim 60.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 61 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehringer Mannheim as previously applied above in view of (Anderson, US 6, 168,948 B1, filing date Jan. 1998). Regarding claims 61 and 64, Boehringer Mannheim et al. teaches a method of RT-PCR wherein a reverse transcription reaction on a RNA sample is conducted to produce a DNA sample and wherein a PCR reagent composition is added to the reaction mixture to conduct the PCR amplification reaction. The method of Boehringer Mannheim differs from the instant invention in that the reference does not teach wherein the reaction mixture and the PCR reagent composition are separated from each other in a reaction vessel by a physical barrier or the reaction is performed in an automated system and wherein the reagents are stored in a cartridge having a plurality of compartments.

Anderson et al. teach a device for performing an amplification reaction wherein said reaction made comprises an automated system and wherein a cartridge is utilized which comprises a plurality of compartments for storage of reagent materials (col. 8-11, section D, and col. 48-40, sections 9 and 11). Anderson et al teach that such a device is useful in various process of genetic diagnosis, in a single process at a minimum cost and with a maximum ease of operation. Therefore, in view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the RT-PCR method of Boehringer Mannheim to encompass a device and cartridge comprising multiple reagent storage compartments and means of automation for the RT-PCR method. One of ordinary skill in the art

would have been motivated to do so for the advantages of a single process which allows genetic diagnosis at a minimum cost and with a maximum ease of operation as taught by Anderson et al.

Closest Prior Art

6. The claims 1-53, 59 and 65-66 are free of the prior art because the prior art does not teach or suggest a method of performing a multiplex PCR reaction or RT-PCR method a first amplification stage and a second amplification state wherein the amplification conditions of the first and second stages are different such that the relative rate of production of a first amplicon is modulated with respect to a second amplicon. Likewise the prior art also does not teach performing a RT-PCR method wherein said reverse transcription reaction is conducted for less than about 10 minutes. The closest prior art, Liu et al. (US 6,355,422 B1) teaches a single tube multiplex amplification reaction wherein the reaction includes a step of subcycling or shuffling, wherein the temperature of the elongation step or a combined annealing/elongation step is sub-cycled or shuffled between at least two temperatures wherein these temperatures are below the denaturation temperature of the PCR product for each full cycle of PCR.

7. Claims 78-86 are free of the prior art and contain allowable subject matter because the prior art does not teach or suggest an intraoperative PCR diagnostic method wherein a PCR method is performed during an operation to determine if the expression of an indicator transcript exceeds a threshold level. For example, Hoon et al. (US 6,057,105) teach a diagnostic method using PCR amplification, wherein a tissue sample suspected of harboring a disease is obtained during an operation, prior to or after an operation and subsequently analyzed by PCR to determine if the expression of an indicator transcript exceeds a threshold level. No motivation

could be found in the prior art for the claimed invention as recited in the instant case. Therefore, an obviousness rejection could not be made.

Conclusion

8. Claims 3, 10, 34, 39, 40, 60, 61 and 64, 81 and 84 are not allowed. Claims 62 and 63 are objected because they depend from a rejected claim. Claims 1-53, 59, 65-66 and 78-86 are free of the prior art and contain allowable subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).